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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,053	12/07/2000	Robert Sullivan	13045-2US-1-	3285

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,053	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/04 has been entered.

2. Claims 1-4 are pending.

3. Claims 1-2 and 4 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claim 3 is being acted upon in this Office Action.

5. Applicant should amend the first line of the specification to update the relationship between the instant application and 09/090,567, filed 6/8/1998, which is now Pat No. 5,989,549.

6. The disclosure is objected to for failing to comply with the requirement of 37 C.F.R. 1.821(d). SEQ ID NO is required in the Brief description of Drawing for Figs 4A-4B and Figs 8A-8B. Appropriate correction is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an immunogenic composition comprising an antigenic protein encoded by nucleic acid comprising the sequence of SEQ ID NO: 3 and (2) an immunogenic composition comprising a polypeptide fragment consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a suitable pharmaceutically acceptable carrier for eliciting an antibody immune response, **does not** reasonably provide enablement for *any* immunogenic

composition comprising an "amino acid fragment having" sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a suitable pharmaceutically acceptable carrier for eliciting any immune response against said fragment after administration to a male or female subject for immunocontraceptive vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a p26h polypeptide, which is an acrosomal sperm protein and is a member of the Short Chain Dehydrogenase/Reductase family, comprising the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1. The specification further discloses two peptides consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a polynucleotide of p34 comprising SEQ ID NO: 3. The specification discloses immunizing a subject with an antigenic fragment of p34 to generate antibodies for diagnosis of male and female infertility.

The specification does not teach how to make and use *any* composition comprising "an amino acid fragment" "having sequence" selected from the group consisting of SEQ ID NO: 4 and 4 because of the following reasons. First, a polypeptide or polypeptide fragment (peptide) makes up of amino acids or an amino acid sequence. Since the amino acid is the smallest unit of a fragment, there is insufficient guidance as how to make, much less how to use "amino acid fragment" for eliciting *any* immune response against said fragment after administration to a male or female subject. Further, the term "having" is open-ended. It expands the sequence of SEQ ID NO: 4 or SEQ ID NO: 5 to include additional amino acids at either or both ends. There is insufficient guidance as to which undisclosed amino acids to be added and whether the resulting polypeptide fragment would generate antibody that binds specifically to SEQ ID NO: 4 or SEQ ID NO: 5 after administration to a male or female subject, in turn, would be useful as a

contraceptive vaccine. Given the indefinite number of amino acid fragment, there is insufficient working example demonstrating that the composition elicits a specific antibody response to SEQ ID NO: 4 or 5. Finally, the specification discloses only antibody immune response against the polypeptide fragment of SEQ ID NO: 4 or SEQ ID NO: 5; the other undisclosed immune response is not adequately taught in the instant specification.

Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al*, of record, teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Given the indefinite number of amino acid fragment, it is unpredictable which undisclosed amino acid fragment in the claimed composition would elicit an antibody response that binds specifically to SEQ ID NO: 4 or SEQ ID NO: 5.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the lack of in vivo working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

9. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* immunogenic composition comprising an "amino acid fragment having" sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a suitable pharmaceutically acceptable carrier

for eliciting any immune response against said fragment after administration to a male or female subject for immunocontraceptive vaccine.

The specification discloses only a p26h polypeptide, which is an acrosomal sperm protein and is a member of the Short Chain Dehydrogenase/Reductase family, comprising the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1. The specification further discloses two peptides consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a polynucleotide of p34 comprising SEQ ID NO: 3. The specification discloses immunizing a subject with an antigenic fragment of p34 to generate antibodies for diagnosis of male and female infertility.

There is inadequate written description about the structure associated with function of any "amino acid fragment having sequence" from the group consisting of SEQ ID NO: 4 and 5 because the term "having" is open-ended. It expands the fragment of SEQ ID NO: 4 and 5 to include additional amino acids at either or both ends. There is inadequate written description about the extra-undisclosed amino acids to be included in the fragment of the claimed composition. Further, the specification discloses only antibody immune response against the polypeptide fragment of SEQ ID NO: 4 or SEQ ID NO: 5; the specification fails to describe the other undisclosed immune response.

Given the lack of an additional representative species of "amino acid fragment" and "immune response", one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 5,989,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 of '549 patent recites an immunocontraceptive vaccine for a male or female subject, which comprises an antigenic fragment (genus) of a P34 protein in association with a suitable pharmaceutically acceptable carrier, wherein said vaccine elicits an immunocontraception response by said male or female subject after its administration. The issuance of a patent to instant claim 3 (species) would anticipate the genus of claim 3 of '549 patent. The antigenic fragment of a P34 protein in the vaccine of the issued patent (genus) includes the immunogenic composition comprising the specific fragment of a P34 protein selected from the group consisting of SEQ ID NO: 4 and 5 (species) of instant application.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

14. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 19, 2004

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